



Attorney Docket No.: P-5235-US15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): DALTON, James T. et al. Examiner: Not yet known  
Serial No.: 10/800,021 Group Art Unit: 1621  
Filed: March 15, 2004  
Title: METHOD FOR DETECTING SELECTIVE ANDROGEN RECEPTOR  
MODULATORS

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☒ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 10/270,232, filed October 15, 2002 and 10/270,233, filed October 15, 2002 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

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SERIAL NO.: 10/800,021  
FILED: March 15, 2004  
Page 2

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

- I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or
- II) ☒ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

APPLICANTS: DALTON, James T. et al.  
SERIAL NO.: 10/800,021  
FILED: March 15, 2004  
Page 3

2. ☒ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

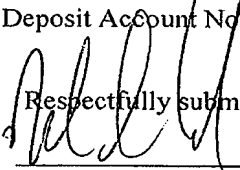
a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,

  
Mark S. Cohen  
Attorney/Agent for Applicant(s)  
Registration No. 42,425

Dated: June 28, 2006

Pearl Cohen Zedek Latzer, LLP  
1500 Broadway, 12th Floor  
New York, New York 10036  
Tel: (646) 878-0800  
Fax: (646) 878-0801



PTO/SB/08a (07-05)  
Approved for use through 07/31/2006. OMB 0651-0031  
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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/800,021
				Filing Date	March 15, 2004
				First Named Inventor	DALTON, James T.
				Art Unit	1621
Examiner Name	Not yet known				
Sheet	1	of	4	Attorney Docket Number	P-5235-US15

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite, No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A	09/935,044		Dalton et al.	08/23/2001	
	B	09/935,045		Dalton et al.	08/23/2001	
	C	09/644,970		Dalton et al.	08/2/2000	
	D	6,019,957		Miller, et al.	02/01/ 2000	
	E	6,071,957		Miller, et al.	06/06/2000	
	F	6,160,011		Miller, et al.	12/12/2000	
	G	4,636,505		Tucker	01/13/ 1987	
	H	4,880,839		Tucker	11/14/ 1989	
	I	4,465,507		Konno, et al.	08/14/1984	
	J	3,875,229		Gold	04/01/1975	
	K	4,139,638		Neri, et al.	02/13/1979	
	L	4,191,775		Glen	03/04/1980	
	M	4,239,776		Glen, et al.	12/16/1980	
	N	4,386,080		Crossley, et al.	05/31/1983	
	O	4,282,218		Glen, et al.	08/04/1981	
	P	5,609,849		Kung	03/11/1997	
	Q	5,162,504		Horoszewicz	11/10/1992	
	R	5,656,651		Sovak, et al.	08/12/1997	
	S	2001/0012839		Miller, et al.	08/09/2001	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite, No. <sup>1</sup>	ForeignPatent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	T	WO	98/53826		Dalton et al.	12/03/1998		
	U	EP	0 100 172		Tucker	02/08/1984		
	V	EP	0 040 932		Crossley et al.	02/12/1981		
	W	WO	95/19770		Gray	07/27/1995		
	X	EP	0253 503		Tucker	12/11/1991		

Examiner Signature	Date Considered
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The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/800,021
				Filing Date	March 15, 2004
				First Named Inventor	DALTON, James T.
				Art Unit	1621
				Examiner Name	Not yet known
Sheet	2	of	4	Attorney Docket Number	P-5235-US15

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	Y	WO	02 00617		Bristol-Myers Squibb	01-03-2002		
	Z	WO	01 27622		Bristol-Myers Squibb	04-19-2001		
	A1	WO	01 28990		Nobex Corporation	04-26-2001		
	B1	WO	01 34563		Nobex Corporation	05-17-2001		
	C1	WO	98 05962		Panvera Corporation	02-12-1998		
	D1	WO	02 016310		Dalton, et al	02-28-2002		
	E1	WO	98 55153		Dalton, et al	12-10-1998		
	F1	WO	95 19770		Sepracor Inc.	07-25-1995		
	G1	WO	02 01630		Dalton, et al	02-28-2002		
	H1	WO	98 55153		Dalton, et al	12-10-1998		
	I1	WO	03 049675		GTx Inc.	06-19-2003		
	J1	WO	03 065992		Gtx Inc.	08-14-2003		
	K1	EP	000 2892		Imperial Chemical Indust.	02-06-1985		
	L1	JP	52-128329		Teikoku Hormone Mfg.	10-27-1977		
	M1	JP	54-63047		Glen, et al	12-16-1980		
	N1	GB	1360001		Neri, et al	03-16-1970		

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Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/800,021
				Filing Date	March 15, 2004
				First Named Inventor	DALTON, James T.
				Art Unit	1621
(use as many sheets as necessary)				Examiner Name	Not yet known
Sheet	3	of	4	Attorney Docket Number	P-5235-US15

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	O1	Howard Tucker and Glynne J. Chesterson, J. Med Chem. 1988, 31, pp. 885-887, "Resolution of the Nonsteroidal Antiandrogen - 4'-Cyano-3-[(4-fluorophenyl)sulfonyl]-2-hydroxy-2-methyl-3'-(trifluoromethyl)-propionanilide and the Determination of the Absolute Configuration of the Active Enantiomer "	
	P1	D. McKillop, et al., "Enantioselective metabolism and pharmacokinetics of Casodex in the male rat", Xenobiotica, 1995, Vol. 25, No. 6, 623-634.	
	Q1	Leonid Kirkovsky, et al., "[ <sup>125</sup> I]-Radionated Bicalutamide Analogs as Potential Imaging Agents for Prostate Cancer", Poster Presentation MEDI 155, 214th ACS National Meeting, Las Vegas, NV, Sept. 7-11, 1997, Department of Pharmaceutical Sciences, University of Tennessee, Memphis, TN 38163	
	R1	David T. Baird and Anna F. Glasier, "Hormonal Contraception - Drug Therapy", The New England Journal of Medicine, May 27, 1993, pp. 1543 - 1549	
	S1	F.C. W. Wu, "Male Contraception: Current Status and Future Prospects", Clinical Endocrinology, (1988), 29, pp. 443-465	
	T1	Carl Djerassi and S.P. Leibo, "A new look at male contraception", Nature, Vol. 370, pp. 11-12	
	U1	World Health Organisation Task Force on Methods for the Regulation of Male Fertility, "Contraceptive efficacy of testosterone-induced azoospermia in normal men", The Lancet, Vol. 336, October 20, 1990, pp. 955-959 and 1517-1518	
	V1	C. G. Francisco, et al., "Long-acting contraceptive agents: testosterone esters of unsaturated acids", Steroids, January 1990, vol. 55, Butterworths	
	W1	John M. Hoberman and Charles E. Yesalis, "The History of Synthetic Testosterone", Scientific American, February 1995, pp. 76-81.	
	X1	Leonid Kirkovsky, et al., "Approaches to Irreversible non-steroidal chiral antiandrogens", Department of Pharmaceutical Sciences, University of Tennessee, 47th Southeast/51st Southwest Joint Regional Meeting of the American Chemical Society, Memphis, TN, Nov. 29-Dec. 1, 1995	
	Y1	David J. Handelsman, "Bridging the gender gap in contraception: another hurdle cleared" The Medical Journal of Australia, Vol. 154, February 18, 1996, pp. 230-233.	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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				Application Number	10/800,021
				Filing Date	March 15, 2004
				First Named Inventor	DALTON, James T.
				Art Unit	1621
				Examiner Name	Not yet known
Sheet	4	of	4	Attorney Docket Number	P-5235-US15

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	Z1	Edwards JP, Higuchi RI, Winn DT, Pooley CLF, Caferro TR, Hamann LG, Zhi L, Marschke KB, Goldman ME, and Jones TK. Nonsteroidal androgen receptor agonists based on 4-(trifluoromethyl)-2H-pyrano[3,2-g]quinolin-2-one. Bioorg. Med. Chem. Lett., 9: 1003, 1999.	
	a	Zhi L, Tegley CM, Marschke KB, and Jones TK. Switching androgen receptor antagonists to agonists by modifying C-ring substituents on piperidino[3,2-g]quinolone. Bioorg. Med. Chem. Lett., 9: 1009, 1999.	
	b	Higuchi RI, Edwards JP, Caferro TR, Ringgenberg JD, Kong JW, Hamann LG, Arienti KL, Marschke KB, Davis RL, Farmer LJ, and Jones TK. 4-Alkyl- and 3,4-diaklyl-1,2,3,4-tetrahydro-8-pyridono[5,6-g]quinolines: potent, nonsteroidal androgen receptor agonists. Bioorg. Med. Chem. Lett., 9:1335,1999.	
	c	Hamann LG, Mani NS, Davis RL, Wang XN, Marschke KB, and Jones TK. Discovery of a potent, orally active nonsteroidal androgen receptor agonist: 4-ethyl-1,2,3,4-tetrahydro-6-(trifluoromethyl)-8-pyridono[5,6-g]-quinoline (LG121071). J. Med. Chem., 42: 210, 1999.	
	d	Rosen J, Day A, Jones TK, Jones ET, Nadzan AM, and Stein RB. Intracellular receptors and signal transducers and activators of transcription superfamilies: novel targets for small-molecule drug discovery. J. Med. Chem., 38: 4855, 1995.	
	e	Dalton JT, Mukherjee A, Zhu Z, Kirkovsky L, and Miller DD. Discovery of Nonsteroidal Androgens. Biochem. Biophys. Res. Commun., 244(1):1-4, 1998.	
	f	Edwards JP, West SJ, Pooley CLF, Marschke KB, Farmer LJ, and Jones TK. New nonsteroidal androgen receptor modulators based on 4-(trifluoromethyl)-2-(1H)-Pyrololidino[3,2-g]quinolone. Bioorg. Med. Chem. Lett., 8: 745, 1998.	
	g	Eliason et al., "High Throughput Fluorescence Polarization-Based Screening Assays for the Identification of Novel Nuclear Receptor Ligands," Abstracts of Papers, 223rd ACS National Meeting, Orlando, FL, United States, (2002), April 7, 2002	
	h	Berger et al., "Concepts and limitations in the application of radiolabeled antiandrogens, estrogens, or androgens as isotropic scanning agents for the prostate", Invest. Urol, (1975), 1391, 10-16	

Examiner Signature		Date Considered	
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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